

# Qalitex Cautions Against Overreliance on Accelerated Stability Data for Product Launches

*Qalitex warns brands not to rely solely on accelerated stability data, emphasizing need for real-time studies to validate shelf-life and product performance.*

IRVINE, CA, UNITED STATES, July 1, 2025 /EINPresswire.com/ -- [Qalitex Laboratories](#) has issued a new advisory urging manufacturers in the personal care and consumer goods sectors to reexamine their dependence on accelerated stability testing when determining product shelf life. The California-based analytical laboratory reports that while accelerated protocols serve a role in forecasting degradation, they should not replace real-time data when supporting expiration dating or product release.



Accelerated testing is commonly used to simulate long-term storage by subjecting products to elevated temperature and humidity. These conditions are designed to speed up chemical and physical changes that might occur under standard conditions. However, Qalitex notes that these simulations may not always reflect real-world outcomes across diverse formulation types and packaging systems.

## Limitations of Accelerated Protocols

According to ICH Q1A(R2), accelerated stability testing is intended to provide early insight into a product's behavior under stress. In most cases, the goal is to observe degradation patterns and estimate shelf life prior to the availability of long-term data.

Qalitex warns that such projections may not account for certain types of degradation that emerge gradually under ambient conditions. Some degradation pathways—such as moisture-driven reactions, microbial growth, or light-induced breakdown—can behave differently outside



Accelerated testing gives you a head start—but it's real-time data that gets you to the finish line with your shelf-life claims intact"

*Nour Abochama, Vice  
President for Operations at  
Qalitex*

of accelerated environments, particularly in complex formulations or temperature-sensitive matrices.

"Accelerated testing has value, but its results must be contextualized," said Nour Abochama, Vice President of Operations at Qalitex. "Real-time data is the only way to confirm that a product remains stable under actual storage and distribution conditions."

## Regulatory Expectations for Shelf-Life Documentation

Under current FDA requirements, expiration dates must be supported by scientific evidence demonstrating product stability throughout the stated shelf life. For [cosmetic products](#), similar expectations are set by regulations such as the EU Cosmetic Regulation (EC) No. 1223/2009 and ISO 22716. While accelerated studies may be used initially, regulators often request real-time data to confirm those findings, especially during inspections or audits.

Qalitex has observed that brands relying solely on accelerated studies may face documentation challenges when submitting shelf-life support to retailers or regulators. In the absence of real-time data, firms may be required to conduct additional testing, adjust labeling, or respond to compliance holds.

## Packaging and Distribution Considerations

Shelf-life projections based on accelerated testing assume consistent storage conditions and packaging performance throughout distribution. Qalitex emphasizes that temperature variations, humidity fluctuations, and light exposure during transportation or storage may fall outside the original test parameters.

For instance, products tested in sealed containers under controlled lab settings may not account for exposure during warehouse storage, retail display, or last-mile delivery. Changes to packaging materials, distribution methods, or storage environments after initial testing may also affect product stability.

"Packaging validation must be aligned with both test conditions and actual usage scenarios," Abochama said. "Even minor changes can require additional verification."

## Pressure from Product Launch Timelines

Qalitex acknowledges that product development timelines can place pressure on stability testing schedules. Accelerated testing offers a faster path to initial shelf-life projections, allowing labels and packaging to be finalized more quickly. However, launching a product without a plan to

confirm those projections over time may introduce long-term quality risks.

“Without real-time verification, early shelf-life decisions may not hold up under field conditions,” Abochama said.

### Best Practices for Integrated Stability Programs

Qalitex recommends that manufacturers use accelerated testing as a predictive tool—one that should be followed by real-time stability studies that span the full intended shelf life.

Recommended approaches include:

Launching with conservative expiration dates, to be extended once real-time data is collected

Running accelerated and real-time tests in parallel during initial production cycles

Including multiple product lots and packaging types to assess variability

Tracking changes to formulations, packaging, or logistics that may require new stability testing

Products containing moisture-sensitive ingredients, microbial preservatives, or materials with known stability constraints may warrant earlier and more extensive real-time data collection.

### Considerations for Private Label and Contract Manufacturers

Brands that outsource manufacturing or operate under private label agreements may receive stability data based primarily on accelerated testing. Qalitex advises these brands to verify whether real-time studies are in progress and request access to the underlying data for recordkeeping and audit preparedness.

Failure to confirm long-term validation may complicate responses to platform compliance checks, regulatory inspections, or retailer documentation requests.

### Ongoing Support for Data-Driven Shelf-Life Validation

Qalitex provides tailored stability testing services that include both accelerated and real-time protocols, based on a product’s category, storage conditions, and intended market. Each study is designed to support scientifically defensible shelf-life claims that align with current regulatory and commercial expectations.

“Accelerated testing helps forecast performance, but it does not confirm it,” Abochama said. “Our role is to support clients with the data they need to validate their products over time.”

For more information about Qalitex’s stability testing and product validation services, visit [www.qalitex.com](http://www.qalitex.com).

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